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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/627,568	07/24/2003	Ronald C. Montelaro	I 2000.608 US C1	3285

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EXAMINER	
LI, BAO Q	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 06/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/627,568	MONTELARO ET AL.	
	Examiner	Art Unit	
	Bao Qun Li	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 March 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-10 and 14-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 3-10 and 14-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. The amendment filed on 2/21/06 has been acknowledged. Because it comply the amendment rule, it has been entered. Claims 1, 3-10 and 14-16 have been amended. Claims 2 and 11-13 were canceled. Claims 1, 3-10 and 14-16 are pending and considered before the examiner.

Figure

2. The new Figures 2a, 2b, 6, 7 and 9 have been acknowledged and entered.

Specification

3. The correction of the typographic error in the specification has been acknowledged and entered.

Declaration

4. The declaration filed on October 28, 2005 under 37 CFR 1.131 has been considered. However, it is objected because on the record that Li Feng and Craigo, Jodi are legal inventors of current application as stated in the Oath/ Declaration originally filed. If applicants considered that they are not inventors for the current application, a petition for CORRECTION OF INVENTORSHIP under RULE 47 / 48 is required.

5. Moreover, The declaration filed on October 28, 2005 under 37 CFR 1.131 is insufficient to overcome the rejection by the reference of Li et al. (A) because Li et al. (A)'s reference is a statutory bar under 35 U.S.C. 102(b) and thus cannot be overcome by an affidavit or declaration under 37 CFR 1.131.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

7. Claims 1, 5 and 9 are still rejected under 35 U.S.C. 112 second paragraph for the same ground as stated in the previous office action, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. In the response, applicants do not response to the question raised in the previous office action regarding where the claimed deletion is made in the claimed genetic engineered EIAV construct. Because the location of the deletion is not defined, it is unclear which gene lacks the expression as claim drafted too. Therefore, the rejection is maintained.

Claim Rejections under 35 USC § 102(b)

9. Applicants are reminded that a reasonable broad interpretation of the substitution mutation contains a deletion of a previous amino acid and replace it with a different amino acid in the same position. Because applicants do not specify what kind of the mutation it is considered as a deletion mutation in claim 1, the rejection is based on this reasonable interpretation only on the record.

10. Claims 1, 3 and 4 are rejected under 35 U.S.C. 102(b) as being anticipated by Li et al. (A) (J. Virol. 1998, Vol. 72, No. 10, pp. 8344-8348).

11. In response to the office action, applicants has filed a Declaration under 1.131 and submit that the reference by Li et al. (A) (J. Virol. 1998, Vol. 72, No. 10, pp. 8344-8348) can be considered as prior art because Li Feng and Bridge A. Puffer worked under Dr. Montelaro R.

12. The declaration filed on October 28, 2005 under 37 CFR 1.131 is insufficient to overcome the rejection by the reference of Li et al. (A) because Li et al. (A)'s reference is a statutory bar under 35 U.S.C. 102(b) and thus cannot be overcome by an affidavit or declaration under 37 CFR 1.131.

Withdrawn of the Rejections under 35 USC § 102 (a)

13. The Declaration by Declaration by Dr. Montelaro R. under 37 CFR ***§ 1.131*** has been acknowledged and it found persuasive to overcome the rejection over the reference by Li et al. (B) (J. Virol. January 2000, Vol. 74, No. 1, pp. 573-579).

14. However, applicants are reminded that the objection of the Declaration under 1.131 is required to be overcome. Otherwise, the withdrawn rejection is considered as a provisional, it could be resumed and then be made Final.

15. (The examiner apologizes the typographic error for the rejected claims in the previous office action, wherein the rejected claims should be 1, 3 and 4)

16. New Ground rejections:

Claim Rejections - 35 USC § 102/103

17. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

18. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

19. Claims 1, 3 and 4 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Li et al. (A) (J. Virol. 1998, Vol. 72, No. 10, pp. 8344-8348).

20. The claimed invention is directed to a genetically engineered nucleic acid construct comprising the two stop codons in the EIAV's S2 open reading frame and a deletion in S2 gene. any wherein in a gene of the EIAV genetic construct.

21. Li, et al. teach a genetically engineered EIAV construct, i.e. EIAV.2M/X that comprises insertions of two redundant stop codons at the positions G5 and G18, wherein the insertion of the stop codons can be considered that the original amino acid methenion at position 18 is deleted. To this context, the claimed invention is anticipated by the cited reference.

22. Or alternative, Li et al. (A) also teach a method for deletion of some nucleotides of S2 gene, such as a deletion of the first 5 nucleotides of S2 gene that is able to only inactivate the S2 gene expression without interrupting the EIAV envelope protein expression.

23. To this context, it would have been obvious for a person with ordinary skill in the art to be motivated for making a recombinant EIAV construct that comprising deletion of the first 5

nucleotides of S2 gene in addition of insertion of two redundant stop codons in the S2 gene because both mutations have been approved to only inactivate the S2 gene expression without interrupt the envelope protein expression of the EIAV gene.

24. As there are no unexpected results have been provided, hence the claimed invention as a whole is prima facie obvious absence unexpected results.

Claim Rejections - 35 USC § 102/103

25. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

26. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

27. Claims 1, 3 and 4 are rejected under 35 U.S.C. 102(e) as being anticipated by Montelaro et al. (A) (US patent NO. 6, 528,250B1).

28. The applied reference has a common inventor and Assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

29. In the instant case, Montelaro et al. in Patent "258B1" teach a method for making EIAV mutated construct comprising the inserting two redundant stop codons in G5 and G18, wherein the insertion of the stop codons can be considered that the original amino acid methenion at position 18 is deleted. To this context, the claimed invention is anticipated by the cited reference.

30. Or alternative, Monteralo et al. (A) also teach a method for deletion of some nucleotides of S2 gene or deletion of DU gene , wherein such as deletion in combination with inserting two redundant two stop codons in the construct are all able to only inactivate the S2 gene expression without interrupting the EIAV envelope protein expression.

31. To this context, it would have been obvious for a person with ordinary skill in the art to be motivated for making a recombinant EIAV construct that comprising deletion of the first 5 nucleotides of S2 gene in addition of insertion of two redundant stop codons in the S2 gene because both mutations have been approved to only inactivate the S2 gene expression without interrupt the envelope protein expression of the EIAV gene.

32. As there are no unexpected results have been provided, hence the claimed invention as a whole is prima facie obvious absence unexpected results.

Claim Rejections - 35 USC § 103

33. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

1. Claims 1, 3, 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Li et al. (A) (J. Virol. 1998, Vol. 72, No. 10, pp. 8344-8348) and Lichtenstein et al. (J Virol. 1995, Vol. 69, No. 5, pp. 2881-2888).

34. The claimed invention is directed to a genetically engineered nucleic acid construct comprising the two stop codons in the EIAV's S2 open reading frame and a deletion in a gene of the EIAV genetic construct.

35. Li, et al. teach a genetically engineered EIAV construct, i.e. EIAV.2M/X that comprises insertions of two redundant stop codons at the positions G5 and G18, wherein the insertion of the stop codons can be considered that the original amino acid methenion at position 18 is deleted. Li et al. (A) do not teach how to inactive other gene of the EIAV that does not influence the expression of the envelope protein of EIAV.

36. Lichtenstein et al. teach a method for deleting the EIAV DU gene without influence the expression of the envelope protein of EIAV (Se pages 2882).

37. Therefore, it would have been obvious for a person with ordinary skill in the art to making a construct that comprising both S2 gene and DU gene mutations made by the methods taught by Li et al. (A) and Lichtenstein et al., wherein the mutated EIAB construct is still able to replicate and express its envelop protein as the reference already approved.

38. Because the cited references together clearly teach that the attenuated EIAV or EIAV vector can be made by deleting the S2 and/or DU gene without influencing the viral replication and with increasing the vector's capacity as well as reducing the detrimental effect caused by the S2 and/or DU gene in contact, the claimed invention as a whole is prima facie obvious absent unexpected results.

39. Claims 1, 3, 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Li et al. (A) (J. Virol. 1998, Vol. 72, No. 10, pp. 8344-8348) and Montelaro et al. (B). US patent NO. 1,461,616B1).

40. Li, et al. teach a genetically engineered EIAV construct, i.e. EIAV.2M/X that comprises insertions of two redundant stop codons at the positions G5 and G18, wherein the insertion of the stop codons can be considered that the original amino acid methenion at position 18 is deleted. Li et al. (A) do not teach how to inactive other gene of the EIAV that does not influence the expression of the envelope protein of EIAV.

41. Montelaro et al. (B) teach a method for making an EIAV mutant that comprises deletion of part of the gag gene p26, wherein the mutant does not change the ability for expressing the EIAV envelop protein and use it as an immunogenic composition for producing a significant immune response against EIAV infection (See Fig. 1 and claims 1-11).

42. Therefore, it would have been obvious for a person with ordinary skill in the art to be motivated for making a genetic engineered EIAV construct comprising both S2 gene and p26 gene mutations and use the construct as an immunogenic composition to produce an immune response. Absence of any unexpected result to the contrary, the claimed invention as a whole is prima facie obvious absent unexpected results.

43. Claims 1, 3, 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Li et al. (A) (J. Virol. 1998, Vol. 72, No. 10, pp. 8344-8348) and Kingsman (WO 99/32646 A1).

44. Li, et al. teach a genetically engineered EIAV construct, i.e. EIAV.2M/X that comprises insertions of two redundant stop codons at the positions G5 and G18, wherein the insertion of the stop codons can be considered that the original amino acid methenion at position 18 is deleted. Li et al. (A) do not teach how to inactive other gene of the EIAV that does not influence the expression of the envelope protein of EIAV.

45. Kingsman et al. teaches that a retroviral EIAV can be constructed without both S2 and DU (dUTPase) gene as a genetic vaccine construct in order to eliminate deleterious effects caused by the accessory genes and increase the package capacity of a heterologous gene inserted. The viral vector lacking such accessory genes does not influence the vector production or transduction in either dividing or non-dividing cells (See lines 18-30 on page 4 and example 7 on page 40 through 42). Kingsman et al. also teaches that the vector can carry any heterologous nucleotide sequence of interest (NOI) suitable for the therapeutic and/or diagnostic application (see the lines 15 on page 9 through line 20 on page 10).

46. Therefore, it would have been obvious for a person with ordinary skill in the art to be motivated for making a genetic engineered EIAV construct comprising both S2 gene and DU gene mutations and use the construct as an immunogenic composition to produce an immune response. Absence of any unexpected result to the contrary, the claimed invention as a whole is prima facie obvious absent unexpected results.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 571-272-0904. The examiner can normally be reached on 6:30 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Bao Qun Li